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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,930	03/22/2001	Ellen Heber-Katz	00486.00006	1820

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,930	HEBER-KATZ, ELLEN	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 15, 19, 21, 22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 19, 21, 22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09-15-2003 has been entered.

Election/Restriction

Claims 3-5 are maintained as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claim Rejections - 35 USC § 112

The rejection of record of claims 1, 2, 15-22, 24 and 25 under 35 U.S.C. 112, second paragraph, set forth in the prior Office action (mailed 06-17-2003) is withdrawn in response to applicant's amendments filed 09-15-2003.

The rejection of record of claims 1, 2, 15-22, 24 and 25 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter), set forth in the prior Office action (mailed 06-17-2003) is withdrawn in response to applicant's amendments filed 09-15-2003.

Response to Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 depends from claim 1 and provides the limitation that the wounding of the heart occurs concomitant with wounding. Claim 1 is specifically directed to methods wherein a mammal already has a heart wound, prior to administration of a thyroid-lowering agent. It is unclear how the wounding occurs both before and concomitantly with wounding.

Claim Rejections - 35 USC § 102

The rejection of record of claims 1, 2, 17-19, 24 and 25 under 35 U.S.C. 102(b) as being anticipated by Chappel et al. (Endocrinology, 1959, 65, p 208-215) is withdrawn in response to Applicant's amendments filed 09-15-2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 16-19, 21 and 22 are maintained as rejected and claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Treadwell et al. (Obstetrics and Gynecology, May 1996, 87, 5 pt 2, pages 838-840).

Treadwell et al. disclose a method wherein a human fetus is treated by oral maternal administration of propylthiouracil, effective to lower levels of total T3 in the fetus to a level lower than the level of a human which has not been administered PTU (see for example, Table 1, which indicates that the total T3 was lowered to 40 ng/dL which is 83% lower than the level of a normal human (233 ± 2.0 ng/dL)). The fetus presented with pericardial effusion prior to treatment, which would cause damage to the pericardium, and falls within the scope of a “heart wound”. This damage would be expected to continue while the effusion persisted, including damage that would occur concomitant to administration of propylthiouracil, prior to reduction of the effusion. Treatment resulted in the resolution of fetal hydrops, which would include the pericardial effusion. Treadwell et al. do not explicitly state that propylthiouracil heals damage to the pericardium of the heart or that re-epithelialization occurs, however, propylthiouracil induces healing and re-epithelialization and, therefore, this activity would be expected to be inherent to the methods disclosed by Treadwell et al., given that the methods of Treadwell et al. comprise all of the method steps of the claimed methods. Therefore, Treadwell et al. anticipate claims 1, 2, 16-19, 21, 22 and 26.

Claims 1, 2, 16-19, 21, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Corte, et al. (Gazz Med Ital Arch Aci Med, 1993, 152:149-153), as evidenced by Refetoff et al. or Loos et al. or Alain et al.

Corte et al. disclose increasing healing of an ischemic heart in a human patient by administering propylthiouracil, after the ischemic injury occurred. Corte et al. does not state that re-epithelization occurs, however, since this property is associated with PTU, and the method of Corte et al. comprises all of the steps of the instantly claimed method, this would be inherent to the methods disclosed by Corte et al. Corte et al. further disclose detecting increased healing of the heart wound in the treated patient. The levels of thyroid hormone T3 and T4 are lowered at least 80% relative to mammals which have not been administered PTU, as evidenced by Refetoff et al. or Loos et al. or Alain et al. Refetoff et al., Loos et al. and Alain et al. each disclose examples wherein humans, not administered PTU, have T3 and T4 levels which are at least 80% higher than the T3 and T4 levels of the patient disclosed by Corte et al., after treatment with PTU.

Therefore, Corte et al. anticipates claims 1, 2, 16-19, 21 and 23-26.

Response to Arguments

Applicant's arguments filed 09-15-2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 1, 2, 16-19, 21 and 22 under 35 USC 102(b) as anticipated by Treadwell et al. Applicant argues that Treadwell has not met all of the limitations of the claimed method. Applicant argues that the

mother is treated with propylthiouracil to correct hyperthyroidism and the direct effects of thyroxin on the fetal heart, which is unrelated to the treatment of a heart wound in the fetus. This has not been found persuasive because the propylthiouracil administered to the mother is also delivered to the fetus and the heart wound in the fetus is healed. Since the thyroid hormone lowering agent is provided using the same method as claimed, it would be expected that healing of the heart wound in the fetus was increased by the thyroid hormone lowering agent. The method steps are the same and, therefore, the outcome would be expected to be the same even if that outcome is not explicitly stated, absent evidence to the contrary. Applicant further argues that the amendment "by at least 80% relative to the T3 or T4 thyroid hormone level in a second mammal" also distinguishes the claimed method from Treadwell et al. This is not found to be persuasive, as set forth in the rejection under 102(b) as anticipated by Treadwell et al. set forth herein, for example, Table 1 of Treadwell et al. indicates that the total T3 was lowered to 40 ng/dL, which is 83% lower than the level of a normal human (233 ± 2.0 ng/dL) and is also greater than 80% lower than other mammals, not administered propylthiouracil disclosed in the art (see for example, mammals disclosed by Refetoff et al. or Loos et al. or Alain et al.). Therefore, Treadwell et al. meets all of the limitations of the claimed methods.

Claim Objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 specifies that the wounding of the heart occurs prior to administration of the thyroid lowering hormone, however, parent claim 1 already requires that the thyroid lowering agent be administered to a mammal which already has a heart wound, therefore, claim 21 does not further limit claim 1.

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

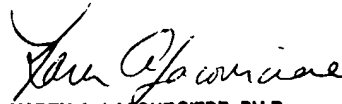
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
November 19, 2003



KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER